

Claims

1. A recombinant poxvirus, wherein the poxvirus genome does not comprise a functional gene encoding a 3β -hydroxysteroid dehydrogenase/ Δ^5 - Δ^4 isomerase, for use as a medicament.

5

2. A recombinant poxvirus as claimed in claim 1 for use as a vaccine against a disease caused by a poxvirus.

3. A recombinant poxvirus as claimed in claim 1 or claim 2
10 wherein the recombinant poxvirus is an orthopoxvirus or a derivative thereof.

4. A recombinant poxvirus as claimed in claim 1 or claim 2
15 wherein the recombinant poxvirus is a vaccinia virus, a cowpox virus, a camelpox virus or an ectromelia virus or a derivative of any of those viruses.

5. A recombinant poxvirus as claimed in claim 1 or claim 2
20 wherein the recombinant poxvirus is a vaccinia virus.

6. A recombinant poxvirus as claimed in claim 5 wherein the recombinant poxvirus is a vaccinia virus strain selected from the group consisting of Lister, Copenhagen, Wyeth, New York City Board of Health, NYVAC, Praha virus, DRYVAX
25 Wyeth-derived virus, LIVP, IHD-J, IHD-W, Tian Tan, Tashkent, King Institute, Patwadanger, EM-63, Evans, Bern, LC16m0 or MVA.

7. A recombinant poxvirus as claimed in claim 6 wherein the
30 recombinant poxvirus is a vaccinia virus strain selected

from the group consisting of MVA, Lister, Copenhagen or Wyeth.

8. A recombinant poxvirus as claimed in any one of claims 3
5 to 7 for use as a vaccine against a disease caused by an orthopoxvirus infection in a human.

9. A recombinant poxvirus as claimed in claim 8 wherein the
disease caused by an orthopoxvirus is selected from the
10 group consisting of smallpox, monkeypox, and cowpox.

10. A recombinant poxvirus as claimed in claim 9 wherein
the disease caused by an orthopoxvirus is smallpox.

11. A recombinant poxvirus as claimed in any one of claims
15 3 to 7 for use as a vaccine against a disease caused by an orthopoxvirus infection in an animal.

12. A recombinant poxvirus as claimed in claim 11 wherein
20 the animal is a mammal.

13. A recombinant poxvirus as claimed in claim 11 or 12
wherein the disease caused by an orthopoxvirus is selected
from the group consisting of monkeypox, cowpox, and
25 camelpox.

14. A recombinant poxvirus as claimed in claim 1 or claim 2
wherein the recombinant poxvirus is selected from the group
consisting of parapoxviruses, avipoxviruses, suipoxviruses,
30 molluscipoxviruses and yatapoxviruses.

15. A recombinant poxvirus as claimed in claim 14 for use as a vaccine against a disease caused by a poxvirus infection in a human.

5 16. A recombinant poxvirus as claimed in claim 14 or 15 for use as a vaccine against a disease caused by a molluscum contagiosum virus infection in a human.

10 17. A recombinant poxvirus as claimed in claim 14 or 15 for use as a vaccine against a disease caused by a poxvirus infection in an animal wherein the poxvirus is selected from the group consisting of parapoxviruses, avipoxviruses, suipoxviruses, molluscipoxviruses and yatapoxviruses.

15 18. A recombinant poxvirus as claimed in claim 17 wherein the animal is a mammal.

19. A recombinant poxvirus as claimed in any one of claims 1 to 18 in which the poxvirus has no coding sequence
20 encoding a 3β -hydroxysteroid dehydrogenase/ Δ^5 - Δ^4 isomerase.

20. A recombinant poxvirus as claimed in any one of claims 1 to 18 in which the gene encoding a 3β -hydroxysteroid dehydrogenase/ Δ^5 - Δ^4 isomerase is disrupted, mutated or
25 truncated such that its gene product has reduced activity.

21. A recombinant poxvirus as claimed in any one of claims 1 to 18 in which one or more mutations or deletions in the promoter or other upstream sequences of the gene encoding a
30 3β -hydroxysteroid dehydrogenase/ Δ^5 - Δ^4 isomerase cause

expression of the gene to be compromised, leading to reduced levels of gene expression.

22. A recombinant poxvirus as claimed in any one of claims 1 to 21 wherein the poxvirus genome comprises a non-poxvirus gene or a fragment of a non-poxvirus gene which gene or fragment encodes an antigen.

23. A vaccine composition comprising a poxvirus as defined in any one of claims 1 to 22 and a pharmaceutically suitable carrier.

24. A vaccine composition as claimed in claim 23 further comprising one or more additives selected from the group comprising a preservative, a stabiliser and an adjuvant.

25. A vaccine kit comprising a composition as claimed in claim 23 or 24.

26. A method of vaccinating a subject comprising administering to the subject an immunogenic agent, wherein the immunogenic agent is a poxvirus as defined in any one of claims 1 to 22 or a vaccine composition as claimed in claim 23 or 24.

27. Use of a recombinant poxvirus having a genome which does not comprise a functional gene encoding a 3β -hydroxysteroid dehydrogenase/ Δ^5 - Δ^4 isomerase for the manufacture of a vaccine for the immunoprophylaxis of an infection caused by a poxvirus.

28. A recombinant poxvirus having a genome comprising a non-poxvirus gene or a fragment of a non-poxvirus gene which gene or fragment encodes an antigen, wherein the poxvirus genome does not comprise a functional gene
5 encoding a 3β -hydroxysteroid dehydrogenase/ Δ^5 - Δ^4 isomerase, for use as a medicament.

29. A recombinant poxvirus as claimed in claim 28 wherein the poxvirus is an orthopoxvirus or a derivative thereof.

30. A recombinant poxvirus as claimed in claim 28 or claim 29 wherein the poxvirus is a vaccinia virus, a cowpox virus, a camelpox virus or an ectromelia virus, or a derivative of any of those viruses.

31. A recombinant poxvirus as claimed in claim 28 or claim 29 wherein the poxvirus is a vaccinia virus.

32. A recombinant poxvirus as claimed in claim 31 wherein the poxvirus is a vaccinia virus strain selected from the group consisting of Lister, Copenhagen, Wyeth, New York City Board of Health, NYVAC, Praha virus, DRYVAX Wyeth-derived virus, LIVP, IHD-J, IHD-W, Tian Tan, Tashkent, King Institute, Patwadanger, EM-63, Evans, Bern, LC16m0 and MVA.

33. A recombinant poxvirus as claimed in claim 32 wherein the poxvirus is a vaccinia virus strain selected from the group consisting of MVA, Lister, Copenhagen or Wyeth.

34. A recombinant poxvirus as claimed in any one of claims 28 to 33 in which the non-poxvirus gene or gene fragment

that encodes an antigen is a non-poxvirus gene or gene fragment against the gene product of which a protective immune response in a subject is desirable.

5 35. A recombinant poxvirus as claimed in any one of claims 28 to 34 for use as a vaccine for the prophylaxis of an infection caused by a pathogenic agent.

36. A recombinant poxvirus as claimed in claim 35 in which
10 the non-poxvirus gene or gene fragment encodes an immunogenic peptide or polypeptide of an infectious pathogen, for example an influenza virus, malaria, HIV, hepatitis C virus, hepatitis B virus, herpes virus, a parasitic pathogen, for example tuberculosis or
15 Leishmaniasis, a protozoan, for example a protozoan that causes ameobic dysentery.

37. A recombinant poxvirus as claimed in claim 28 to 34 for use as a vaccine for the prophylaxis or treatment of a
20 disease associated with aberrant cells.

38. A recombinant poxvirus as claimed in claim 37 in which the non-poxvirus gene encodes an antigenic peptide or polypeptide of aberrant cells, for example cancer cells,
25 the elimination or induced quiescence of which is beneficial.

39. A recombinant poxvirus as claimed in claim 28 or claim 29 wherein the poxvirus is selected from the group
30 consisting of parapoxviruses, avipoxviruses, suipoxviruses, molluscipoxviruses and yatapoxviruses.

40. A recombinant poxvirus as claimed in claim 39 in which the non-poxvirus gene that encodes an antigen is a non-poxvirus gene against the gene product of which a protective immune response in a subject is desirable.

5

41. A recombinant poxvirus as claimed in any one of claims 28 to 40 in which the poxvirus has no coding sequence encoding a 3β -hydroxysteroid dehydrogenase/ Δ^5 - Δ^4 isomerase.

10 42. A recombinant poxvirus as claimed in any one of claims 28 to 40 in which the gene encoding a 3β -hydroxysteroid dehydrogenase/ Δ^5 - Δ^4 isomerase is disrupted, mutated or truncated such that its gene product has reduced activity.

15 43. A recombinant poxvirus as claimed in any one of claims 28 to 40 in which one or more mutations or deletions in the promoter or other upstream sequences of the gene encoding a 3β -hydroxysteroid dehydrogenase/ Δ^5 - Δ^4 isomerase cause expression of the gene to be compromised, leading to
20 reduced levels of gene expression.

44. A vaccine composition comprising a poxvirus as defined in any one of claims 28 to 43 and a pharmaceutically suitable carrier.

25

45. A vaccine composition as claimed in claim 44 further comprising one or more additives selected from the group comprising an antibiotic, a preservative, a stabiliser and an adjuvant.

30

46. A vaccine kit comprising a composition as claimed in claim 44 or 45.

47. A method of vaccinating a subject comprising
5 administering to the subject an immunogenic agent, wherein the immunogenic agent is a poxvirus as defined in any one of claims 28 to 43 or a vaccine composition as claimed in claim 44 or 45.

10 48. Use of a recombinant poxvirus as defined in any one of claims 28 to 36 for the manufacture of a vaccine for the prophylaxis of an infection caused by a pathogenic agent wherein the poxvirus has a genome comprising a non-poxvirus gene or a fragment of a non-poxvirus gene which gene or
15 fragment encodes an antigen of the pathogenic agent.

49. Use of a recombinant poxvirus as defined in any one of claims 28 to 34 or claim 37 or claim 38 for the manufacture of a vaccine for the prophylaxis or treatment of a disease
20 associated with aberrant cells, wherein said poxvirus has a genome comprising a non-poxvirus gene or a fragment of a non-poxvirus gene which gene or fragment encodes an antigen of the aberrant cells comprising the gene product of the said non-poxviral gene.

25

50. A recombinant poxvirus having a genome comprising a non-poxvirus gene or a fragment of a non-poxvirus gene which gene or fragment encodes an antigen, wherein the poxvirus genome does not comprise a functional gene
30 encoding a 3β -hydroxysteroid dehydrogenase/ Δ^5 - Δ^4 isomerase, with the proviso that the non-poxvirus gene or fragment of

a non-poxvirus gene is not a gene encoding varicella-zoster virus glycoprotein E, hepatitis B virus preS2-S protein or *E.coli* guanine phosphoribosyl transferase.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.